Chapter V. Next Steps

This chapter discusses the steps needed to finalize the Level II models (Version 2.0) along with some of the steps necessary to move toward implementation of these models, such as training and outreach.   The chapter concludes with ideas for building partnerships with organizations outside of OPP to refine the Level II models. Several projects, which focus on reducing some of the uncertainties associated with the models, are discussed as well.

A. Finalizing the Level II Models (Version 2.0)

After receiving the SAP's comments and recommendations, OPP will consider and incorporate them, as appropriate, and further develop and refine the models. Finalizing the Level II models will involve the following steps:

- Terrestrial Level II Model - Conduct further sensitivity analysis to define the relationship of the input parameters to the estimates of risk. The inhalation and puddle modules of the model will also be calibrated with existing data.

- QA/QC Plan - Complete documenting the models according to EFED's internal QA/QC guidance and procedures to ensure that models are properly documented and of adequate quality to assess the effects of pesticides on fish and wildlife with specified levels of reliability. This includes the selection of the appropriate standards by which the level of model performance can be judged (e.g., does the model calculate aerobic half-life as it was designed to do). This internal QA/QC guidance has been approved by the OPP Quality Assurance Manager and is currently in use in EFED (Appendix L).

- Beta-Testing - Conduct beta testing, focusing on rigorous case studies which will test all of the features and components of the models. In these studies, different pesticide examples will be used with varying amounts of data and levels of risk. The results of beta-testing will also be compared for consistency, and the adequacy of the instructions for using the model will be evaluated. Participants will include EFED scientists, but may be expanded to other OPP divisions and other EPA offices to provide an outside perspective.

- Model Maintanance - Develop procedures and mechanisms for maintaining the models. As the models are used, additional modifications may be necessary.

B. Training

Training for risk assessors and risk managers is critical to implementing the Level II models. Risk assessors will need to know how and when to conduct a Level II probabilistic assessment and how to develop a transparent, clear, consistent and reasonable risk characterization. Risk managers will also need to participate in training to ensure they fully understand the basic components of the models, the resulting risk characterization, and when

probabilistic assessments should be conducted.

1. Risk Assessors

Training will include background information on the use of risk assessment software, basic and advanced statistics, and how to conduct a probabilistic assessment. Once the background courses have been completed, training will focus on the use of the Level II models. The course will include a training manual/user's guide, which will be the primary source of information for using the Level II models. This comprehensive guide will include an overview of the model and the various modules, system resource requirements, guidance regarding input parameters, reporting results, and other related topics. The training will include case studies and a risk assessment exercise.

Training will also include information on developing a robust risk characterization for communicating the key findings of the assessment, strengths and weaknesses, and a description of the uncertainties and assumptions. Emphasis will be placed on developing risk characterizations that are transparent, clear, consistent, and reasonable.

Training for scientists outside of OPP has been discussed and may include short courses at professional meetings such as the Society for Environmental Toxicology and Chemistry.

2. Risk Managers

The Division plans to provide briefings that include an overview and demonstration workshops. The workshops may include an overview of Level II models and case studies to illustrate how the models work with a comparison to the probabilistic assessments conducted for human health.

It is critical that a discussion of risk characterization be included in both briefings and workshops. Risk managers need to thoroughly understand this final component of the risk assessment process because it synthesizes the conclusions and provides a summary of assumptions, scientific uncertainties, and the strengths and weaknesses of the analysis.

3. Risk Assessors and Risk Managers

A workshop focusing on when to conduct a probabilistic assessment using the Level II models is also being planned. Workshop participants will use a problem formulation case study and participate in a planning dialogue which considers management goals and options, the scope and complexity of the risk assessment, timeframe, and available resources. To maximize the benefit of this workshop, risk managers and risk assessors, who are both critical to the problem formulation stage of a risk assessment, will be invited to participate.

C. Outreach

Outreach is an essential element in implementing a probabilistic approach to ecological risk assessment. Keeping other government agencies, academia, contract laboratories, environmental advocacy groups, and industry informed provides an open and transparent process. One of the key tools that OPP will use to inform the public is the following Web site for this initiative.

http://www.epa.gov/oppefed1/ecorisk/index.htm

Access to the Level II models and presentations to professional societies will be available on this Web site. In the near future, OPP plans to expand the Web site to include an overview of the screening level assessment, which is conducted at Level I.

To inform the states and other stakeholders, OPP plans to provide updates on the Level II models to the Pesticide Program Dialogue Committee and the State FIFRA Issues Research and Evaluation Group. OPP is also planning a series of briefings for other federal agencies, such as the U.S. Fish and Wildlife Service and the U.S. National Oceanic and Atmospheric Administration. Another outreach venue will be the EPA Probabilistic Risk Assessment Colloquium, which will occur later this year and involve other EPA offices such as the Office of Water, Office of Research and Development, Office of Solid Waste and Emergency Response, and EPA Regions.

To ensure maximum scientific exchange and discussion, the Agency plans to participate in nationally recognized professional meetings, such as the Society for Environmental Toxicology and Chemistry as well as international workshops, such as the European Workshop on Probabilistic Risk Assessments for the Environmental Effects of Plant Protection Products (EUFRAM), and meetings with the Organization for Economic Cooperation and Development (OECD) Ad Hoc Risk Assessment Advisory Body, and Canada's Pest Management Regulatory Agency.

D. Building Partnerships and Future Directions

By continuing to build on existing partnerships, OPP will be better positioned to refine the Level II models and create synergies with other Agency programs to reach common goals. For example, OPP has been collaborating with EPA's Office of Research and Development (ORD) on several projects of interest, which focus on reducing significant model uncertainties. Both offices plan to participate in a meeting with the SAP in the future to discuss the progress and findings of these projects and receive feedback on future directions. OPP also hopes to expand its collaboration efforts to include other agencies and stakeholders as well.

1. Addressing Uncertainties Related to Effects Characterization

a. Extrapolation Research for Predicting Toxicological Responses

Currently the Level II Aquatic Model uses standardized aquatic toxicity tests and a

classical statistical method (e.g., normal distribution of Log LC50's) to determine species sensitivity distributions. A key area of uncertainty results when not enough data are available to use a classical statistical method. The extrapolation methods currently available are limited and a comprehensive review of newer data sets is needed to establish more realistic and less uncertain extrapolation factors.

In response to this need, ORD began to work on identifying and compiling a collection of data sets on acute and chronic toxicity, across chemical modes of action, to aquatic species that would be relevant and applicable to the standardized aquatic toxicity tests currently used to support pesticide registration. These data sets have been identified, and the distribution of toxicity across taxa and the inter- and intra-species variability in toxicity is being evaluated for its utility to establish distributions for relevant taxa.

ORD's Aquatic Stressors Research Plan (EPA-600-R-02-074), which describes ORD research supporting EPA's Office of Water (OW), includes similar or identical approaches for developing methods for extrapolating chemical toxicity data across endpoints, life stages and species. Integration of ORD's research related to reducing extrapolation uncertainties across program offices will result in greater harmonization of general approaches and the state-of-the-science techniques applied within OPP and OW. Additional harmonization in the development and application of extrapolation methods and tools will result from OPP's collaboration with ORD and OW scientists in an on-going effort to revise the OW's guidelines for deriving ambient water quality criteria.

b. Advancing Techniques for Assessing Risk of Pesticides

A major area of uncertainty not currently addressed by the terrestrial Level II model is avian reproduction impairment. This area of uncertainty has been discussed since ECOFRAM was convened early in the initiative. During the ECOFRAM deliberations and in subsequent discussion, there was a consensus that the current avian reproduction test would need to be redesigned for use in probabilistic assessments. These tests need to provide a dose-response relationship based on the ingested daily dose instead of the current use of hypothesis testing to determine dietary concentration.

ORD has been examining the overall approach for evaluating pesticide effects on avian reproduction and what laboratory testing can and cannot provide. OPP will be working with ORD to discuss their findings regarding technical issues involved with methods for defining dose-response relationships, what information is needed to address questions about the magnitude of pesticide effects to wild birds, and the potential for modified avian reproduction tests to achieve these goals.

In the future, assessment techniques will also need to be explored for addressing mortality and chronic effects to mammals and amphibians.

2. Addressing Exposure Uncertainties

a. Database of Regional Small Surface Water Body Characteristics

An area of uncertainty in the exposure component of the aquatic Level II model concerns the input values for the model. These values include watershed size, volume, depth, pH, and other key characteristics that influence the representation or extrapolation of the exposure model for these waters. To reduce this uncertainty and to improve the accuracy of exposure predictions, field data are needed. Once the data are collected, a database of regional small surface water body (e.g., depressional wetlands, temporary and permanent pools and ponds) characteristics will be developed.

In response to this need, ORD is exploring a census and landscape indicator approach for deriving these input values for small surface water bodies in specific hydrological landscapes in the Midwest. This project is part of a larger landscape indicator approach for pesticides and nutrients in stream water and in streambed sediments and aquatic biological conditions in selected small streams in specific hydrological landscapes in the Midwest. Although limited in scale, the data generated should provide useful empirical information to refine components of the exposure model and potentially provide a method(s) to extrapolate these characteristics and their distributions on a broad scale.

b. Initial Application Date

The aquatic Level II model will be refined to incorporate an initial application date as a uniform distribution rather than a single input date. This change will be incorporated to reduce the uncertainty about application date due to the sensitivity of the exposure output to the selection of the initial application day. For example, random selection of the initial application date, within a two week window for three pesticides with different environmental half-lives, resulted in differences between the smallest and highest annual peak for a given year of 3.8 fold for a relatively non-persistent to moderately persistent pesticides and only about 1.4 fold for a persistent pesticide.

c. Development of Uncertainty and Extrapolation Factors for Metabolism Rate Constants for Use in Modeling

Generally limited data are available to estimate the metabolic rate constants for input into OPP's runoff and surface water models, which leads to high uncertainty in the results of the modeling. As a result, extrapolation and uncertainty factors are used. However, they are based on a fairly limited data set and a formal evaluation of the underlying distributions or effect of the number of studies on the magnitude of uncertainty has not been conducted. Analyses of a large data base of rate constants needs to be evaluated to determine the nature of the distributions of each kind of metabolism data. The magnitude of the variability in each type of data, the amount of uncertainty incurred by using a limited number of data sets, and the nature of the correlations between study types also need to be evaluated. The results of these analyses will be used to reevaluate the extrapolation and uncertainty factors currently used.

3. Predictions of Population Dynamics

Risk managers, who determine how a pesticide will be regulated, are interested in receiving information concerning the probability and magnitude of population impacts from the use of a pesticide. Working in collaboration with OPP, ORD will develop tools that will provide risk managers with spatially-explicit, population-level risk assessments. These tools will allow the Agency to (1) extrapolate toxicological data across species and exposure scenarios of concern, (2) predict population-level responses and for identifying the responses at the individual level that have the greatest influence on a population response, (3) assess the relative risk of chemical and non-chemical stressors on populations across large areas, and (4) refine exposure estimates to provide spatially-explicit, probabilistic exposure models.